Boehringer Ingelheim Pharmaceuticals, Inc.

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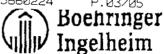
Gentlemen:

Boehringer Ingelheim Pharmaceuticals, Inc (BIPI) provides the following information and suggestions to the EPA regarding the issues by the June 3rd Federal Register Notice and raised at the June 18th public hearing on Hazardous Waste in Research Laboratories. BIPI strongly believes that there are several inherent flaws in the agency's RCRA rules and the rules as crafted do recognize the specific needs and issues raised in research laboratories. A few simple changes to the rules would make management of the waste much easier without in anyway compromising environmental protection.

Laboratory waste is typically generated in very small quantities and becomes "discarded" at variable periods depending on many other events. Typically a material will be held until analytical results confirm or deny the research has yielded the desired end product. Even after a disappointing result, that is not to say the material is ready to be discarded as further purification or processing may produce the desired result or a different but useful end point. This leads to several opportunities:

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- Training hundreds of scientists on the subtly of RCRA rules is not good use of their time or the environmental staff. While the researchers need to follow established procedures, the determination of hazardous versus non hazardous can best be done by the environmental staff at a common location not in each satellite accumulation area (i.e. each laboratory). The researcher should be adequately trained in waste practices, not in all the obligations of RCRA. One way this is achieved is to have the point of generation should be the location at which laboratory waste are co-mingled.
- Since laboratory waste is typically generated in very small quantities, making each lab a satellite accumulation area is not always workable. Many laboratories would prefer to co-mingle the waste in a large container (typically 55 or 30 gallon drums). However the definition of "under the control of the generator" would suggest that everyone using the container must have the container in his line of sight or other similar impossible configurations. A way to resolve this, is again, the point of generation is not the lab but either the location of commingling or where a RCRA specialist examines the material.
- Labeling small vials of waste is clearly impossible when one discusses containers of 1 or 2 milliliters capacity. The laboratory that generated the material or the scientist lab can be placed on the outside of a container that co-mingles many smaller containers. The RCRA specialist can then judge from his knowledge of what transpires in the laboratory, whether or not a specific vial meets the hazardous waste definition. Keep in mind the most serious flaw in the current RCRA rule is that there is NO de minimis quantity on manifest. Hence a vial with 5 micrograms of mercury has the same regulatory obligations of a 76 pound flask. This becomes very onerous when the paper work is considered. A lab pack can have 30 to 40 pages of individual descriptions of very small vials. By providing an exemption for detailing small vials of hazardous waste headed for the same treatment, the Agency would make for more efficient waste disposal process.

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- Requiring full containers to be retrieved in 3 days can be a problem when smaller cans, such as 5 gallon safety cans, are used for waste storage. The reality is, that it requires a full time person to do nothing but run around a large site collecting cans which could just as easily be picked up on a regularly scheduled basis. In some places, 55 gallons of waste are accumulated in SAA In those cases, moving the drums within three days of being full is logical. A one week collection period for smaller containers would seem to be justified. It would in no manner degrade the environmental protection practices already provided by the collection process. In fact, use of smaller containers less than 20 liters affords a great degree of environmental protection and safety because it minimizes the extent and volume of incidental spills. An exclusion that grants generators the ability to store full containers less than 20 liters for 7 days should be considered.
 - 5. Laboratory personnel do neutralize waste but they should also be allowed to deactivate reactive material. This would mean "neutralizing" unconsumed reactant with a quenching agent or other process steps. In fact such process steps are frequently considered art of the process rather than a treatment step, but deactivation should be made part of the allowable treatment processes that do not require TSDF status.
 - device drains into a holding container. Some interpretations would suggest that these containers are part of the process; others have suggested they are each indeed SAA. A clear policy interpretation or guidance that the discarding occurs not when the machine rejects the material but when the operator removes the container from the machine would be useful.

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The holistic way to make these changes workable is to require each laboratory setting that handles small quantities of waste (e.g. largest vessel size in the lab is less than 20 liters) have a hazardous waste management plan that requires training, segregation and treatment of the waste such that all determinations of RCRA applicability can be made outside the lab while still requiring a level of practice that adequately protects the environment. Where laboratories support production activities, the current rules are not onerous in a pure research environment, they cause considerable inefficiency in training, collection and disposal practices.

We would be pleased to demonstrate our waste management practices at the Ridgefield, Connecticut site or more fully describe how the RCRA regulations are really strained when they are applied to research laboratories.

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Thank you for your consideration.

Very truly yours,

Arthur E. Slesinger

Environmental Affairs and Safety Corporate Director, E